PTO/SB/21 (09-04) /
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|   | Application Number   | 10/613         | ,078                        |   |
| O P ETRANSMITTAL  | Filing Date  | July 1,        | 2003                        |   |
| آرِ∕ FORM   | First Named Inventor   | John S         | . Patton et a               | 1.                                      |
| 2 8 2005  | Art Unit   | 1615           |                             |   |
| 302   | Examiner Name  | Kishor         | e .                         | <u> </u>                                |
| To be used to the correspondence uner mind ming)  | Attorney Docket Number   | 0005.1         |                             |   |
| (to be used for all correspondence after initial filing)  |  | 10003.1        |                             |   |
|   | NCLOSURES (Check al  | that appl      | y)                          |   |
| Fee Transmittal Form  Fee Attached  Amendment/Reply  After Final  Affidavits/declaration(s)  Extension of Time Request  Express Abandonment Request  Information Disclosure Statement  Certified Copy of Priority Document(s)  Reply to Missing Parts/ Incomplete Application  Reply to Missing Parts under 37 CFR 1.52 or 1.53 | Drawing(s)  Licensing-related Papers  Petition Petition to Convert to a Provisional Application Power of Attorney, Revocation Change of Correspondence of Terminal Disclaimer  Request for Refund  CD, Number of CD(s)  Landscape Table on Cleemarks | Address        | Approf Approf (Approf State | •                                       |
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| Signature Luy Vice  | li   |                |                             |   |
| Printed name Guy V. Tucker  |  |                |                             |   |
| Date 22. 10v 2005   |  | Reg. No.       | 45,302                      |   |
| CERTIFICATE OF TRANSMISSION/MAILING   |  |                |                             |   |
| I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:                   |  |                |                             |   |
| Signature Munico (  | otta   |                |                             |   |
| Typed or printed name Minna Cotter  |  |                | Date                        | 225405                                  |

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: John S. Patton et al.

Atty. Docket No.: 0005.16

Examiner: Kishore

Application No.: 10/613,078

Filed: 07/01/2003

Title: METHODS AND COMPOSITIONS
FOR THE PULMONARY DELIVERY
OF INSULIN

OF INSULIN

Atty. Docket No.: 0005.16

Examiner: Kishore

Group Art Unit: 1615

OF INSULIN

#### **CERTIFICATE OF MAILING**

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Signed: Menina Catter

# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.56, §1.97 and §1.98

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Dear Sir:

The references listed in the attached Forms PTO/SB/08A and B may be material to examination of the above-identified patent application. Applicants submit these references in compliance with their duty of disclosure pursuant to 37 CFR §§1.56, 1.97, and 1.98. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that these references indeed constitute prior art.

Copies of the references are enclosed, as required under 37 CFR §§1.98.

This Information Disclosure Statement is being timely filed under 37 CFR §§1.97 and is being filed:

|             |             | within three months of the filing date of a national application or an RCE; within three     |
|-------------|-------------|--|
|             |             | months of the date of entry of the national stage as set forth in section 1.491 in an        |
|             |             | international application; or before the mailing date of a first Office action on the        |
|             |             | merits (whichever event occurs last);  |
|             | $\boxtimes$ | more than three months from the filing date of an application and after the mailing date     |
|             |             | of a first Office action on the merits, but before the mailing date of either a final action |
|             |             | under section 1.113 or a notice of allowance under section 1.311 (whichever occurs           |
|             |             | first), and is accompanied by:   |
|             |             | the fee set forth in 37 CFR 1.17(p) for submission of an information                         |
|             |             | disclosure statement under §1.97(c) (\$180.00)   |
| $\boxtimes$ | Please      | charge the amount of \$180.00 to Deposit Account 500348                                      |
| $\boxtimes$ | If it is    | determined that any additional fees are due, the Commissioner is hereby authorized to        |
|             | charge      | such fees to Deposit Account 500348.   |
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|             |             | Respectfully submitted,  |
|             |             | NEKTAR THERAPEUTICS  |
| Dated:      | 22)         | By: Juny V. Tucker   |
|             |             | Reg. No. 45,302  |
|             |             |  |

| Form PTO/SB/08A (Modified) |                                   | Atty Docket No.:      | Application No.: |  |
|----------------------------|-----------------------------------|-----------------------|------------------|--|
|                            |                                   | 0005.16               | 10/613,078       |  |
|                            | Information Disclosure            | Applicant:            |                  |  |
| Statement By Applicant     |                                   | John S. Patton et al. |                  |  |
|                            |                                   | Filing Date:          | Group:           |  |
| (c)                        | (Use Several Sheets if Necessary) | 07/01/2003            | 1615             |  |

**U.S. Patent Documents** 

| \$1                |                                       | U.S. I atem  | Documents      |       |               |                |
|--------------------|---------------------------------------|--------------|----------------|-------|---------------|----------------|
| Xaminer<br>Initial | Detect No                             | Data         | Dadamása       | Class | Sub-          | Filing<br>Date |
| ımuaı              | Patent No.                            | Date         | Patentee       | Class | Class         | Date           |
|                    | 4,952,402                             | 08/28/1990   | Sparks et al.  |       |               |                |
|                    | 5,006,343                             | 04/09/1991   | Benson et al.  |       |               |                |
|                    | 5,049,389                             | 09/17/1991   | Radhakrishnan  |       |               |                |
|                    | 5,225,183                             | 07/06/1993   | Purewal et al. |       |               |                |
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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Form PTO/SB/08A (Modified)        | Atty Docket No.:      | Application No.: |  |
|-----------------------------------|-----------------------|------------------|--|
|                                   | 0005.16               | 10/613,078       |  |
| Information Disclosure            | Applicant:            |                  |  |
| Statement By Applicant            | John S. Patton et al. |                  |  |
|                                   | Filing Date:          | Group:           |  |
| (Use Several Sheets if Necessary) | 07/01/2003            | 1615             |  |

### Foreign Patent or Published Foreign Patent Application

| Examiner |     | Document  | Publication | Country or    |       | Sub-  | Trans | lation |
|----------|-----|-----------|-------------|---------------|-------|-------|-------|--------|
| Initial  | No. | No.       | Date        | Patent Office | Class | class | Yes   | No     |
|          |     | 0 257 915 | 03/02/1988  | EP            |       |       |       |        |
|          |     | 0 407 028 | 01/09/1991  | EP ,          |       |       |       |        |
|          |     | 0 520 748 | 12/30/1992  | EP            |       |       |       |        |
|          |     | 0 582 459 | 02/09/1994  | EP .          |       | ·     |       |        |
|          |     | 0 606 486 | 07/20/1994  | EP            |       |       |       |        |
|          |     | 1,122,284 | 08/07/1968  | GB.           |       |       |       |        |
|          |     | 1,182,779 | 03/04/1970  | GB            |       |       |       |        |
|          |     | 90/13285  | 11/15/1990  | WO .          |       |       |       |        |
|          |     | 90/13328  | 11/15/1990  | WO            |       |       |       |        |
|          |     | 91/11179  | 08/08/1991  | WO -          |       |       |       |        |
|          |     | 94/00291  | 01/06/1994  | WO            |       |       |       | _      |
|          |     | 94/16717  | 08/04/1994  | WO ·          |       |       |       |        |
|          |     | 95/00128  | 01/05/1995  | WO            |       |       |       |        |
|          |     | 95/11666  | 05/04/1995  | WO            |       |       |       |        |
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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

| Form PTO/SB/08B (Modified)        | Atty Docket No.:      | Application No.: |  |
|-----------------------------------|-----------------------|------------------|--|
|                                   | 0005.16               | 10/613,078       |  |
| Information Disclosure            | Applicant:            |                  |  |
| Statement By Applicant            | John S. Patton et al. |                  |  |
|                                   | Filing Date:          | Group:           |  |
| (Use Several Sheets if Necessary) | 07/01/2003            | 1615             |  |

### **Other Documents**

| Examiner | ПТ  |   |
|----------|-----|---|
| Initial  | No. | Author, Title, Date, Place (e.g. Journal) of Publication  |
|          |     | GRAHAM ET AL., "An in-vitro test for the duration of action of insulin suspension", J. of Pharm. Pharmocol., <u>36</u> (7):427-430, (1984 Jul.), Abstract |
|          |     | HEUBNER ET AL., "Über Inhalation Von Insulin", J. Klia. Wochenschrift, 3(28):2342-2343  |
|          |     | SCHLUTER ET AL., "Pulmonary Administration of Human Insulin in Volunteers and Type 1-Diabetics," 75A, 298, (1984)   |
|          |     | VIDGREN ET AL., "In Vitro and In Vivo Deposition of Drug Particles Inhaled from Pressurized Aerosol and Dry Powder Inhaler", pp. 2649-2665, (1988)        |
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